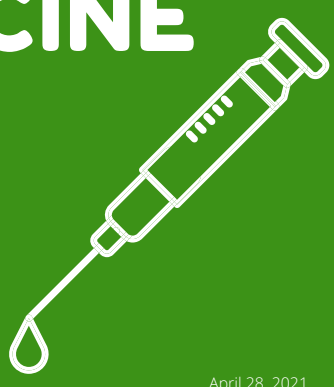
JANSSEN COVID-19 VACCINE IS SAFE, HERE'S WHY

The vaccine DOES NOT contain the virus that causes COVID-19 and cannot give you COVID-19. It also cannot make you sick from the virus that is used as the vector. It cannot change your DNA in any way.



April 28, 2021

BASIC RESEARCH

Researchers have been paying attention to related coronaviruses and developing faster ways to manufacture vaccines.

Scientists began creating viral vectors in the 1970s. For decades, hundreds of scientific studies of viral vector vaccines have been done, with studies published around the world, including to fight against other infectious diseases such as Zika, flu, and HIV.

Source: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/viralvector.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Fhcp%2Fviral-vector-vaccine-basics.html

DISCOVERY

The SARS-CoV-2 genome was discovered in January 2020.

On January 9, 2020, the World Health Organization (WHO) announced the discovery of a novel coronavirus, and by January 30, the Institut Pasteur in France shared the whole genetic sequence of the virus.

Source: https://www.sciencedaily.com/releases/2020/01/200131114748.htm

PRECLINICAL TRIALS

Before clinical trials can begin, important feasibility, replicability and safety data are collected, typically in laboratory animals.

The typical 8+ month process was sped up by using research methods and platforms developed for other diseases.

Source: https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/

Investigational New Drug (IND) application submitted to the FDA "to ensure that subjects will not face undue risk of harm in a clinical investigation of a drug".

Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4435682/

PHASE 1 CLINICAL TRIALS

The first trials to study the success of the vaccine in humans began in Spring 2020.

The goal of these trials is to determine if the vaccine is effective, if there are side effects, and what size dose is effective while minimizing side effects.

Source: https://www.cdc.gov/vaccines/basics/test-approve.html

PHASE 2 CLINICAL TRIALS

Throughout Summer 2020, hundreds of volunteers participated in trials of the COVID-19 vaccines.

Through these trials, researchers learn the most common short-term side effects and how volunteers' immune systems are responding.

Source: https://www.cdc.gov/vaccines/basics/test-approve.html

Fact: **In the final stages of trials, it helped that COVID-19 was everywhere because firms need infections to show that vaccines work. It's hard to run efficacy trials when the diseases themselves aren't prevalent.**

Source: https://www.nature.com/articles/d41586-020-03626-1

Fact: **The COVID-19 vaccines went through the same trials, but the billions poured into the process made it possible for companies to take financial risks by running some tests at the same time. This meant that companies could gamble on starting large-scale testing and manufacturing of candidates that might not work out.**

Source: https://www.nature.com/articles/d41586-020-03626-1

PHASE 3 CLINICAL TRIALS

The typical 42-month phase was able to speed up because of the volunteers available, and no steps were compromised or missed.

30,000 demographically diverse volunteers allowed researchers to examine how vaccine recipients' immune responses compared to those who didn't receive a vaccine.

Source: https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/

Fact: **Clinical trials don't stop here. Monitoring of these vaccines and research into their long-term effectiveness will continue for years.**

Source: https://www.cdc.gov/vaccines/basics/test-approve.html

Biologics License Application (BLA) submitted to the FDA demonstrating compliance with product and establishment standards.

Source: https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber

FDA REVIEW

The typical 12-month review was shortened as data was shared throughout Phase 3 Clinical Trials.

Instead of waiting until trials were complete, researchers shared data about the safety and effectiveness of the vaccines throughout their trials.

Source: https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/

ACIP REVIEW

Comprised of medical and public health experts, the ACIP makes recommendations on the use of vaccines in the United States.

The Janssen vaccine was authorized for use in the U.S. in February 2021. In April, Janssen was paused out of an abundance of caution. On April 23, 2021, the ACIP review panel determined that the benefits far outweighed any associated risks of receiving the Janssen vaccine.

Source: https://www.nature.com/articles/d41586-020-03626-1

MORE COVID-19 VACCINE INFORMATION: **CDH.IDAHO.GOV/COVID-VACCINE.PHP**

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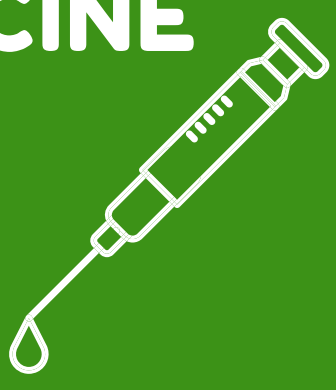

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FACT: THE RISK OF SEVERE ADVERSE SIDE EFFECTS FROM THE JANSSEN VACCINE IS EXTREMELY LOW.

In April, ACIP and CDC recommended vaccination with the Janssen vaccine resume among people 18 years and older. Women younger than age 50 should be aware of the rare but increased risk of thrombosis with thrombocytopenia syndrome (TTS). TTS is a serious condition that involves blood clots with low platelets.

The Janssen vaccine may also referred to as the Johnson & Johnson, J&J, JnJ, or Triple J vaccine.

FACT: COVID-19 VACCINES WILL NOT GIVE YOU COVID-19.

None of the COVID-19 vaccines currently in development in the U.S. use the live virus that causes COVID-19. The Moderna and Pfizer vaccines in use contain mRNA and the Janssen vaccine uses a viral vector.

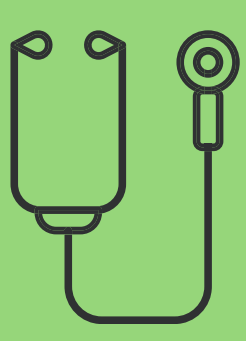
FACT: RECEIVING A VIRAL VECTOR VACCINE WILL NOT ALTER YOUR DNA

Coronaviruses, like the one that causes COVID-19, are named for the crown-like spikes on their surface, called spike proteins. These spike proteins are ideal targets for vaccines.

A viral vector vaccine uses a harmless version of a different virus, called a “vector,” to deliver information to the body that helps it protect you.

The viral vector vaccine teaches your body how to make copies of the spike proteins. If you are exposed to the real virus later, your body will recognize it and know how to fight it off.

FACT: YOU WILL NOT BE IMMEDIATELY IMMUNE TO COVID-19 FOLLOWING VACCINATION.



It typically takes a few weeks for the body to build immunity after vaccination. That means it’s possible a person could be infected with the virus that causes COVID-19 just before or just after vaccination and become infected. This is because the vaccine has not had enough time to provide protection against the virus. It will continue to be recommended that vaccinated people follow COVID precautions (face coverings, distancing, etc.) until herd immunity is developed.

FACT: THE JANSSEN VACCINE IS A ONE-DOSE VACCINE.

Unlike the Moderna and Pfizer two-dose vaccines, Janssen only requires one shot.

FACT: COVID-19 VACCINES WILL NOT CAUSE YOU TO TEST POSITIVE ON COVID-19 VIRAL TESTS.

Vaccines currently available in the U.S. won’t cause you to test positive on viral tests, which are used to see if you have a current COVID-19 infection. When your body develops an immune response, which is the goal of vaccination, you could test positive on some COVID-19 antibody tests, which indicate either past infection or immune response to a COVID-19 vaccine.

FACT: PEOPLE WHO HAVE GOTTEN SICK WITH COVID-19 MAY STILL BENEFIT FROM GETTING VACCINATED.

Due to the severe health risks associated with COVID-19 and the fact that re-infection with COVID-19 is possible, it is recommended that people get a COVID-19 vaccine even if they were infected with the virus that causes COVID-19. Some early evidence suggests natural immunity may not last very long.

FACT: GETTING VACCINATED CAN HELP PREVENT GETTING SICK WITH COVID-19.

While many people with COVID-19 have only a mild illness, others may get a severe illness or they may even die. There is no way to know how COVID-19 will affect you, even if you are not at increased risk of severe complications. If you get sick, you also may spread the disease to friends, family, and others around you while you are sick. COVID-19 vaccination helps protect you by creating an antibody response without having to experience disease.

Source: https://coronavirus.idaho.gov/covid-19-vaccine/

MORE COVID-19 VACCINE INFORMATION: **CDH.IDAHO.GOV/COVID-VACCINE.PHP**